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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.		
10/635,928	08/06/2003	Balaji Venkataraman	52761-0110 (286146)	1053		
23370 JOHN S. PRAT	7590 12/22/2006 T. ESO		EXAM	EXAMINER		
KILPATRICK STOCKTON, LLP			HENRY, MICHAEL C			
1100 PEACHTREE STREET ATLANTA, GA 30309			ART UNIT	PAPER NUMBER		
, -			1623			
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SHORTENED STATUTOR	Y PERIOD OF RESPONSE	MAIL DATE	DELIVER	DELIVERY MODE		
3 MO	NTHS	12/22/2006	PAP	PAPER		

# Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary		Application No.					
		10/635,928					
		Examiner	Art Unit				
	·	Michael C. Henry	1623				
Period fo	The MAILING DATE of this communication ap or Reply	pears on the cover sheet with the	correspondence addre	ess			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.138(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).							
Status							
1) 又	Responsive to communication(s) filed on 26 S	September 2005.					
		s action is non-final.					
3)	<i>,</i> —						
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Dispositi	ion of Claims						
4)⊠	4)⊠ Claim(s) <u>1-5,7-12,15-19,22-31 and 33-47</u> is/are pending in the application.						
	4a) Of the above claim(s) is/are withdrawn from consideration.						
5)	5) Claim(s) is/are allowed.						
6)⊠	6)⊠ Claim(s) <u>1-5,7-12,15-19,22-31 and 33-47</u> is/are rejected.						
7)	7) Claim(s) is/are objected to.						
8)□	8) Claim(s) are subject to restriction and/or election requirement.						
Applicati	on Papers						
9)☐ The specification is objected to by the Examiner.							
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.							
	Applicant may not request that any objection to the	drawing(s) be held in abeyance. Se	e 37 CFR 1.85(a).				
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).							
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
Priority u	ınder 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:							
	1. Certified copies of the priority documents have been received.						
	2. Certified copies of the priority document	·					
	3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.							
		2 23 25pi35 no. 1000110	- <b></b>				
Attachma=1							
Attachment(s)  1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)							
2) 🔲 Notice	e of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Da	ate				
	nation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date <u>08/22/05</u> .	5)  Notice of Informal F 6)  Other:	atent Application				

#### **DETAILED ACTION**

The following office action is a responsive to the Amendment filed, 09/26/05.

The amendment filed 09/26/05 affects the application, 10/635,928 as follows:

- Claims 35-37 have been amended. Claims 6, 13, 14, 20, 21, 32 have been canceled.
   New Claims 44-47 have been added. This leaves claims 1-5, 7-12, 15-19, 22-31, 33-
  - 47. The office action mailed 06/20/06 is withdrawn is withdraw.
- 2. The responsive to applicants' arguments is contained herein below.

Claims 1-5, 7-12, 15-19, 22-31, 33-47 are pending in application

### Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-19, 22, 24, 30, 33 and 41-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "a condition associated with a hormonal change" in claims 15, 24 and 41-46, renders the claim indefinite. This phrase is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. More specifically, it is unclear what condition (s) are associated with a hormonal change and how must this or these condition be related to the hormonal change to be considered as being associated with the said hormonal change.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 7-12, 23, 25-29, 31, 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paradissis et al. (US 5,494,678) in view of Kostic (Archiv fuer Gynaekologie (1965), 202 (1), pages 506-509).

In claim 1, applicant claims "A composition consisting of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6." Claims 2-5, 7-12, 31, 34 which are further limitations of claim 1, are drawn to specific amounts of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6, and specific kinds of vitamins B12 (i.e. hydroxocobalamin) and vitamin D (i.e. vitamin D3). Claim 23 is drawn to composition consisting of calcium, vitamin D, folic acid, hydroxycobalamin (vitamin B12) and vitamin B6. Dependent claims 25-29 are drawn to specific amounts of hydroxocobalamin (vitamin B12) and folic acid.

Paradissis et al. disclose a composition for treating pregnant women comprising calcium, vitamin D, folic acid, vitamin B12, vitamin B6 and vitamin B1 (see abstract and claim 1).

Paradissis et al. disclose that their composition maximizes or optimizes fetal development and maintain the mothers health during the three trimesters of pregnancy (see abstract)

The difference between applicant's claimed composition and the composition of Paradissis et al. is that applicant's composition does not contain vitamin B1.

Kostic discloses that large doses of vitamin B1 (e.g., 100 mg) administered to pregnant women increases uterine contractions in force and frequency (see abstract). Consequently, a skilled artisan would alter Paradissis et al. vitamin composition by removing vitamin B1 from Paradissis et al. vitamin composition in order to administer the composition to pregnant women especially women with specific pregnancy conditions such as women with the high-risk pregnancy (as claimed by applicant) so as to prevent increased uterine contractions that could cause adverse effects or conditions such as premature labor, premature child birth and/or may be a detriment to said pregnant women.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made in view of Paradissis et al. and Kostic to prepare Paradissis et al.'s composition (for pregnant women) and to exclude vitamin B1 in order to administer the composition to pregnant women especially women with specific pregnancy conditions such as women with the high-risk pregnancy (as claimed by applicant) so as to prevent increased uterine contractions that could cause adverse effects or conditions such as premature labor, child birth and/or may be a detriment to said pregnant women, depending on factors such as the medical history, medical health and the daily medications been taken by the women to which the vitamin composition is to be administered.

One having ordinary skill in the art would have been motivated in view of Paradissis et al. to prepare Paradissis et al.'s composition (for pregnant women) and to exclude vitamin B1 in order to administer the composition to pregnant women especially women with specific pregnancy conditions such as women with the high-risk pregnancy (as claimed by applicant) so as to prevent increased uterine contractions that could cause adverse effects or conditions such as

premature labor, child birth and/or may be a detriment to said pregnant women and depending on factors such as the medical history, medical health and the daily medications been taken by the women to which the vitamin composition is to be administered. It should be noted that claims 2-5, 7-12, 23, 25-29, 31, 34 which are drawn to specific amounts of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6 and, specific kinds of vitamins B12 (i.e. hydroxocobalamin) and vitamin D (i.e. vitamin D3) are also encompassed by the aforementioned rejection since the amount or quantity of the components used in the composition depends on factor like the severity of the condition and the mass or age of the pregnant women being treated. In addition, the preparation or alteration of different vitamins and/or minerals formulations consisting of a combination of well-known art recognized vitamins and/or minerals to treat particular conditions, deficiencies, illnesses is also within the purview of an ordinary artisan.

In claim 35, applicant claims "A composition consisting of calcium, vitamin D, folic acid, vitamin B12, vitamin B6 and vitamin C." In claim 36, applicant claims "A composition consisting of calcium, vitamin D, folic acid, vitamin B12, vitamin B6 and iron." In claim 37, applicant claims "A composition consisting of calcium, vitamin D, folic acid, vitamin B12, vitamin B6, vitamin C and iron." Dependent claims 38-40 are drawn to said composition wherein vitamins B12 is hydroxocobalamin.

Paradissis et al. disclose a composition for treating pregnant women comprising calcium, vitamin D, folic acid, vitamin B12, vitamin B6 and vitamin B1 (see col.7, line 45 to col. 8, line 16). Furthermore, Paradissis et al. disclose that this composition may comprise vitamin C and iron (see col.7, line 45 to col. 8, line 16) and that other component including vitamin E, Vitamin

B<sub>2</sub> and B<sub>3</sub> may be absent (i.e., 0 mg) from the said composition (see col.7, line 45 to col. 8, line 16).

The difference between applicant's claimed composition and the composition of Paradissis et al. is that applicant's composition does not contain vitamin B1.

Kostic discloses that large doses of vitamin B1 (e.g., 100 mg) administered to pregnant women increases uterine contractions in force and frequency (see abstract). Consequently, a skilled artisan would alter Paradissis et al. vitamin composition by removing vitamin B1 from Paradissis et al. vitamin composition in order to administer the composition to pregnant women especially women with specific pregnancy conditions such as women with the high-risk pregnancy (as claimed by applicant) so as to prevent increased uterine contractions that could cause adverse effects or conditions such as premature labor, premature child birth and/or may be a detriment to said pregnant women.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made in view of Paradissis et al. and Kostic to prepare Paradissis et al.'s composition (for pregnant women) and to exclude vitamin B1 in order to administer the composition to pregnant women especially women with specific pregnancy conditions such as women with the high-risk pregnancy (as claimed by applicant) so as to prevent increased uterine contractions that could cause adverse effects or conditions such as premature labor, child birth and/or may be a detriment to said pregnant women, depending on factors such as the medical history, medical health and the daily medications been taken by the women to which the vitamin composition is to be administered.

One having ordinary skill in the art would have been motivated in view of Paradissis et al. to prepare Paradissis et al.'s composition (for pregnant women) and to exclude vitamin B1 in order to administer the composition to pregnant women especially women with specific pregnancy conditions such as women with the high-risk pregnancy (as claimed by applicant) so as to prevent increased uterine contractions that could cause adverse effects or conditions such as premature labor, child birth and/or may be a detriment to said pregnant women and depending on factors such as the medical history, medical health and the daily medications been taken by the women to which the vitamin composition is to be administered. It should be noted that claims 2-5, 7-12, 23, 25-29, 31, 34 which are drawn to specific amounts of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6 and, specific kinds of vitamins B12 (i.e. hydroxocobalamin) and vitamin D (i.e. vitamin D3) are also encompassed by the aforementioned rejection since the amount or quantity of the components used in the composition depends on factor like the severity of the condition and the mass or age of the pregnant women being treated. In addition, the preparation or alteration of different vitamins and/or minerals formulations consisting of a combination of well-known art recognized vitamins and/or minerals to treat particular conditions, deficiencies, illnesses is also within the purview of an ordinary artisan.

Claims 1-5, 7-12, 23, 25-29, 31, 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paradissis et al. (US 5,494,678) in view of Boros et al. (Proceedings of the American Association for Cancer Research Annual Meeting, (March, 2000) No. 41, pp. 666. print. Meeting info.: 91<sup>st</sup> Annual Meeting of the American Association for Cancer Research. San Francisco, California, USA. April 01-05, 2000. ISSN: 0197-016X) or Boros (Anticancer Research, (2000) Vol. 20, No, No. 3 B, Pages 2245-2248).

In claim 1, applicant claims "A composition consisting of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6." Claims 2-5, 7-12, 31, 34 which are further limitations of claim 1, are drawn to specific amounts of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6, and specific kinds of vitamins B12 (i.e. hydroxocobalamin) and vitamin D (i.e. vitamin D3). Claim 23 is drawn to composition consisting of calcium, vitamin D, folic acid, hydroxycobalamin (vitamin B12) and vitamin B6. Dependent claims 25-29 are drawn to specific amounts of hydroxocobalamin (vitamin B12) and folic acid.

Paradissis et al. disclose a composition for treating pregnant women comprising calcium, vitamin D, folic acid, vitamin B12, vitamin B6 and vitamin B1 (see abstract and claim 1).

Paradissis et al. disclose that their composition maximizes or optimizes fetal development and maintain the mothers health during the three trimesters of pregnancy (see abstract)

The difference between applicant's claimed composition and the composition of Paradissis et al. is that applicant's composition does not contain vitamin B1.

Boros et al. disclose that vitamin B1 promotes cancer growth (see abstract).

Consequently, a skilled artisan would alter Paradissis et al. vitamin composition by removing vitamin B1 from Paradissis et al. vitamin composition in order to administer the composition to pregnant women especially women with the high-risk pregnancy conditions (as claimed by applicant) and pregnant women with cancer or tumor malignancies or conditions.

Boros discloses that vitamin B1 excess thiamine supplementation contributes to increase cancer rates by enhancing tumor cell proliferation in people of different countries (see abstract and entire article). Consequently, a skilled artisan would alter Paradissis et al. vitamin composition by removing vitamin B1 from Paradissis et al. vitamin composition in order to

administer the composition to pregnant women especially women with the high-risk pregnancy conditions (as claimed by applicant) and pregnant women with cancer or tumor malignancies or conditions.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made in view of Paradissis et al. and Boros et al. or Boros to prepare Paradissis et al.'s composition (for pregnant women) and to exclude vitamin B1 in order to administer the composition to pregnant women especially women with the high-risk pregnancies (as claimed by applicant) so as to prevent the promotion of possible cancer or tumor conditions in said pregnant women due to vitamin B1, depending on factors such as the medical history, medical health and the daily medications been taken by the women to which the vitamin composition is to be administered.

One having ordinary skill in the art would have been motivated in view of Paradissis et al. and Boros et al. or Boros to prepare Paradissis et al.'s composition (for pregnant women) and to exclude vitamin B1 in order to administer the composition to pregnant women especially women with the high-risk pregnancies (as claimed by applicant) so as to prevent the promotion of possible cancer or tumor conditions in said pregnant women due to vitamin B1, depending on factors such as the medical history, medical health and the daily medications been taken by the women to which the vitamin composition is to be administered. It should be noted that claims 2-5, 7-12, 23, 25-29, 31, 34 which are drawn to specific amounts of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6 and, specific kinds of vitamins B12 (i.e. hydroxocobalamin) and vitamin D (i.e. vitamin D3) are also encompassed by the aforementioned rejection since the amount or quantity of the components used in the composition depends on factor like the

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severity of the condition and the mass or age of the pregnant women being treated. In addition, the preparation or alteration of different vitamins and/or minerals formulations consisting of a combination of well-known art recognized vitamins and/or minerals to treat particular conditions, deficiencies, illnesses is also within the purview of an ordinary artisan.

Claims 15-19, 22, 24, 30, 33, 41-45, 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paradissis et al. (US 5,494,678) in view of Kostic (Archiv fuer Gynaekologie (1965), 202 (1), pages 506-509).

In claim 15, applicant claims "A method of treating a condition associated with a hormonal change in an individual comprising administering to the individual an effective amount of a vitamin composition consisting of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6." Claims 16-19 which are further limitations of claim 15, are drawn to specific amounts of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6 and, specific kinds of vitamins B12 (i.e. hydroxocobalamin) and vitamin D (i.e. vitamin D3). Claim 22 is drawn to the method of claim 15, wherein the hormonal change is caused by specific conditions. Claim 46 is drawn to the method of claim 15, wherein the condition with the hormonal change are specific conditions. Claims 24, 30, 33, 41-45, 47 are drawn to a method of treating a condition associated with said hormonal change using specific amounts or quantities of the components in the composition

Paradissis et al. disclose a of treating a condition associated with a hormonal change (pregnancies conditions in women) comprising administering to the individual an effective amount of a vitamin composition for treating pregnant women comprising calcium, vitamin D, folic acid, vitamin B12, vitamin B6 and vitamin B1 (see abstract and claim 1). Paradissis et al.

disclose that their composition maximizes or optimizes fetal development and the maternal mothers health during the three trimesters of pregnancy (see abstract). This implies that Paradissis et al. treats or prevents the fetus underdevelopment and mother's health. It should be noted that pregnancies and the duration thereof are associated with hormonal changes. It should be noted that the cause of the hormonal change does not further limit the condition that is being treated. Furthermore, the condition treated by applicant includes high-risk pregnancy (see applicant's claim 46).

The difference between applicant's claimed method and the method of Paradissis et al. is that applicant's composition does not contain vitamin B1.

Kostic discloses that large doses of vitamin B1 (e.g., 100 mg) administered to pregnant women increases uterine contractions in force and frequency (see abstract). Consequently, a skilled artisan would alter Paradissis et al. vitamin composition by removing vitamin B1 from Paradissis et al. vitamin composition in order to administer the composition to pregnant women especially women with specific pregnancy conditions such as women with the high-risk pregnancy (as claimed by applicant) so as to prevent increased uterine contractions that could cause adverse effects or conditions such as premature labor, premature child birth and/or may be a detriment to said pregnant women.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made in view of Paradissis et al. and Kostic to treat pregnancies conditions in women with Paradissis et al.'s composition (that excludes vitamin B1), by administer the composition to pregnant women especially women with specific pregnancy conditions such as women with the high-risk pregnancy (as claimed by applicant) so as to prevent increased uterine

contractions that could cause adverse effects or conditions such as premature labor, child birth and/or may be a detriment to said pregnant women, depending on factors such as the medical history, medical health and the daily medications been taken by the women to which the vitamin composition is to be administered.

One having ordinary skill in the art would have been motivated in view of Paradissis et al. and Kostic to treat pregnancies conditions in women with Paradissis et al.'s composition (that excludes vitamin B1), by administer the composition to pregnant women especially women with specific pregnancy conditions such as women with the high-risk pregnancy (as claimed by applicant) so as to prevent increased uterine contractions that could cause adverse effects or conditions such as premature labor, child birth and/or may be a detriment to said pregnant women, depending on factors such as the medical history, medical health and the daily medications been taken by the women to which the vitamin composition is to be administered. It should be noted that the use of specific amounts or quantities of the components in the composition depends on factors such as the severity of the condition and the mass or age of individual being treated. It should also be noted that, the preparation or alteration of different vitamins and/or minerals formulations consisting of a combination of well-known art recognized vitamins and/or minerals to treat particular conditions, deficiencies, illnesses is also within the purview of an ordinary artisan.

Claims 15-19, 22, 24, 30, 33, 41-45, 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paradissis et al. (US 5,494,678) in view of Boros et al. (Proceedings of the American Association for Cancer Research Annual Meeting, (March, 2000) No. 41, pp. 666. print. Meeting info.: 91<sup>st</sup> Annual Meeting of the American Association for Cancer Research. San

Francisco, California, USA. April 01-05, 2000. ISSN: 0197-016X) or Boros (Anticancer Research, (2000) Vol. 20, No, No. 3 B, Pages 2245-2248).

In claim 15, applicant claims "A method of treating a condition associated with a hormonal change in an individual comprising administering to the individual an effective amount of a vitamin composition consisting of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6." Claims 16-19 which are further limitations of claim 15, are drawn to specific amounts of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6 and, specific kinds of vitamins B12 (i.e. hydroxocobalamin) and vitamin D (i.e. vitamin D3). Claim 22 is drawn to the method of claim 15, wherein the hormonal change is caused by specific conditions. Claim 46 is drawn to the method of claim 15, wherein the condition with the hormonal change are specific conditions. Claims 24, 30, 33, 41-45, 47 are drawn to a method of treating a condition associated with said hormonal change using specific amounts or quantities of the components in the composition.

Paradissis et al. disclose a of treating a condition associated with a hormonal change (pregnancies conditions in women) comprising administering to the individual an effective amount of a vitamin composition for treating pregnant women comprising calcium, vitamin D, folic acid, vitamin B12, vitamin B6 and vitamin B1 (see abstract and claim 1). Paradissis et al. disclose that their composition maximizes or optimizes fetal development and the maternal mothers health during the three trimesters of pregnancy (see abstract). This implies that Paradissis et al. treats or prevents the fetus underdevelopment and mother's health. It should be noted that pregnancies and the duration thereof are associated with hormonal changes. It should be noted that the cause of the hormonal change does not further limit the condition that is being

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treated. Furthermore, the condition treated by applicant includes high-risk pregnancy (see applicant's claim 46).

The difference between applicant's claimed method and the method of Paradissis et al. is that applicant's composition does not contain vitamin B1.

Boros et al. disclose that vitamin B1 promotes cancer growth (see abstract).

Consequently, a skilled artisan would alter Paradissis et al. vitamin composition by removing vitamin B1 from Paradissis et al. vitamin composition in order to administer the composition to pregnant women especially women with the high-risk pregnancy conditions (as claimed by applicant) and pregnant women with cancer or tumor malignancies or conditions.

Boros discloses that vitamin B1 excess thiamine supplementation contributes to increase cancer rates by enhancing tumor cell proliferation in people of different countries (see abstract and entire article). Consequently, a skilled artisan would alter Paradissis et al. vitamin composition by removing vitamin B1 from Paradissis et al. vitamin composition in order to administer the composition to pregnant women especially women with the high-risk pregnancy conditions (as claimed by applicant) and pregnant women with cancer or tumor malignancies or conditions.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made in view of Paradissis et al. and Boros et al. or Boros to treat pregnancies conditions in women with Paradissis et al.'s composition (that excludes vitamin B1), by administer the composition to pregnant women especially women with specific pregnancy conditions such as women with the high-risk pregnancy (as claimed by applicant) so as to prevent the promotion of possible cancer or tumor conditions in said pregnant women due to

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vitamin B1, depending on factors such as the medical history, medical health and the daily medications been taken by the women to which the vitamin composition is to be administered.

One having ordinary skill in the art would have been motivated in view of Paradissis et al. and Boros et al. or Boros to treat pregnancies conditions in women with Paradissis et al.'s composition (that excludes vitamin B1), by administer the composition to pregnant women especially women with specific pregnancy conditions such as women with the high-risk pregnancy (as claimed by applicant) so as to prevent the promotion of possible cancer or tumor conditions in said pregnant women due to vitamin B1, depending on factors such as the medical history, medical health and the daily medications been taken by the women to which the vitamin composition is to be administered. It should be noted that the use of specific amounts or quantities of the components in the composition depends on factors such as the severity of the condition and the mass or age of individual being treated. It should also be noted that, the preparation or alteration of different vitamins and/or minerals formulations consisting of a combination of well-known art recognized vitamins and/or minerals to treat particular conditions, deficiencies, illnesses is also within the purview of an ordinary artisan.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry

Shaojia Anna Jiang, Ph.D. Supervisory Patent Examiner Art Unit 1623

December 18, 2006.